UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,115	11/14/2005	Trevor Morgan	9013-71	8343

20792 7590 01/23/2007

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,115	MORGAN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-21 are pending and currently under examination.

Priority: The benefit date is February 21, 2003, for the purpose of prior art.

Claim Objections

Claims 8, 11 are objected to because of the following informalities: in claim 8, there should be an "A" preceding the claim; in claim 11, phrase "in the gel in up to 0.5% by weight" is not grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 8, 9, 12, 16, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-6 recite the limitation "fat" in the claim. There is insufficient antecedent basis for this limitation in the claims and their parent claim.

Claim 8 recites comprising less than 5% by weight. It is unclear what is being recited as less than 5% by weight.

Claim 9 recites the porcine collagen comprises collagen derived from young pigs and sows in ratios of 0:100 to 10:90. It is unclear what the ratios of 0:100 to 10:90 are referring to or are of what to what.

Claim 12 recites the limitation "alginate ester" in the claim. There is insufficient antecedent basis for this limitation in the claim and its parent claim.

Claim 16 recites the limitation "the collagen solids content" in the claim. There is insufficient antecedent basis for this limitation in the claim and its parent claim.

Claim 19 is drawn to a method of producing an extruded porcine collagen film, the collagen content consisting essentially of sow collagen, which comprises the recited steps in the claim. The instant claim is drawn to a method, however, the language of the preamble renders the claim indefinite because of the phrase in line 2, the collagen content consisting essentially of sow collagen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 13, 15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckmayer et al. (US 6482240; IDS). Eckmayer et al. teach collagen membranes formed from porcine skins are enzymatically defatted, ground into a gel-like mass, extruded and dried into a collagen membrane (col. 2 lines 59-67; claim 1). Eckmayer et al. teach the collagen membranes can encompass films (col. 1 lines 13). In example 1, Eckmayer et al. teach a method of

producing a porcine collagen film comprising defatting porcine skins by mechanical means (col. 4 line 64), forming a gel-like fluid mass (col. 8 lines 17), and extruding the gel to form a film and/or membrane (col. 10 line 1) (claims 19-20). Eckmayer et al. teach the collagen film can be used as a tube and/or net to wrap around ham (col. 12 lines 16-25; claims 18, 21). The porcine collagen film of Eckmayer et al. has a fat content of about 10% or less by dry weight of the collagen membrane (col. 16 lines 3-6; claims 1, 2-3, 4-6, 7-9, 17). Claims 4-6 are indefinite; therefore, it is believed that the Eckmayer et al. reference meets the limitations of these claims. Additionally, Eckmayer et al. teach the content of the gel-like fluid mass can include glycerol (humectant) and sorbitol (coagulating agent) (col. 8 lines 40-45; claims 13, 15).

Although Eckmayer et al. do not specifically teach the limitation of a wet tear strength greater than 300 gf/mm, this element is anticipated by Eckmayer et al. because Eckmayer et al. teach an extruded porcine collagen film and for a collagen film to be extruded, it must meet the limitations of instant claim 1 and therefore, should inherently have a wet tear strength in the extrusion direction greater than 300 gf/mm (claim 17).

Claims 1, 7-9, 13, 15-18, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank (US 4196223; IDS). Shank teaches a method of preparing sausage casings from pig skins.

The term film, as used in the instant invention, is given its broadest reasonable interpretation and is determined to be functionally equivalent to the casing of Morgan et al. Further, it is noted that the instant specification appears to use the terms film and casing interchangeably.

Shank teaches a collagen gel is prepared from pigskins (col. 2 example 1). The skins are ground and diluted in water to form a paste and then diluted and ground again to give a 3% solids gel (col. 2 lines 43; claim 16). The gel is continuously extruded into a coagulating-tanning bath comprising saturated aqueous sodium chloride containing 2.0 weight percent of glutaraldehyde (col. 2 lines 45-50; claim 15) to form a collagen casing (col. 2 line 51; claim 1, 7-9, 17). The casing is then immersed in a 5% glycerol and water bath (col. 2 line 54; claim 13). Shank teaches the porcine casing can be stuffed with sausage meat, packed, and cooked (col. 1 lines 30-33; claims 18, 21).

Although Shank does not specifically teach the limitation of a wet tear strength greater than 300 gf/mm, this element is anticipated by Shank because Shank teaches an extruded porcine collagen film and for a collagen film to be extruded, it must meet the limitations of instant claim 1 and therefore, should inherently have a wet tear strength in the extrusion direction greater than 300 gf/mm (claim 17).

Claims 1-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan et al. (US 20050031741).

The applied reference has 2 common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The term film, as used in the instant invention, is given its broadest reasonable interpretation and is determined to be functionally equivalent to the casing of Morgan et al. Further, it is noted that the instant specification appears to use the terms film and casing interchangeably.

Morgan et al. teach collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen (p. 1 [0001]-[0002]). In working examples 3-4, Morgan et al. teach a porcine collagen film was prepared from an extrudable porcine collagen gel, having a weight ratio of collagen to fat of around 30:1 (p. 4 [0059]; claims 1, 4-6, 17). The table in paragraph [0062]) indicates a fat percentage of 0.31% and 0.19% for examples 3 and 4, respectively (p. 4; claims 1-3). The porcine collagen casing and/or film in example 20 comprises 6.0% of caprine (goat) collagen on a dry weight basis (p. 12; claims 7-8). Morgan et al. also teach that the collagen properties of the casings can be varied by mixing collagen derived from young pigs (4 mos. old) and older pigs (3 yrs. old) in ratios of 0:100 to 100:0 (p. 2 [0019]; claim 9). In example 12, Morgan et al. teach a porcine collagen casing with a humectant (i.e. glycerol) level of 21.5% on a dry weight basis (p. 8-9; claims 13-14). The collagen casing in example 16 comprises propylene glycol alginate (p. 10; claims 10-12). In example 9, Morgan et al. teach the porcine casing further comprises glutaraldehyde (p. 6 [0128]; claim 15). Also, the collagen casing has a collagen solids content of 7% (p. 13-14; claim 16). In example 1-4, Morgan et al. teach the porcine collagen casings were used to make sausages (p. 3-4; claim 21). The casing of Morgan et al. can also be used to make edible string and/or netting (p. 2 [0022]; claim 18). Further, Morgan et al. teach a method of producing an extruded porcine collagen film from sow collagen comprising soaking sow skins, removing fat by a fleshing machine (p. 3 [0032]),

forming an extrudable gel from the sow skins by blending and disintegrating porcine skin (p. 3 [0039]), and extruding the gel to form a case and/or a film (p. 3 [0040]-[0045]) (claims 19-20).

Although Morgan et al. do not specifically teach the limitation of a wet tear strength greater than 300 gf/mm, this element is anticipated by Morgan et al. because Morgan et al. teach an extruded porcine collagen film that meets the limitations of instant claim 1 and therefore, should inherently have a wet tear strength in the extrusion direction greater than 300 gf/mm (claim 17).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No.

10487955. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '955 claims are both drawn to an extruded porcine collagen film and/or casing made from an extrudable collagen gel, wherein the collagen content consists essentially of sow collagen. It is further noted that both the instant specification and the '955 specification use the terms film and casing interchangeably.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 17, 2007

M. Monshi

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER